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| APPLICATION NO. | FILING DATE                         | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |  |
|-----------------|-------------------------------------|----------------------|-----------------------|------------------|--|
| 10/034,740      | 12/27/2001                          | Bradley J. Enegren   | PF00434 US            | 1376             |  |
| 23608           | 7590 12/15/2004                     |                      | EXAM                  | EXAMINER         |  |
|                 | IC MINIMED INC.                     | NASSER, F            | NASSER, ROBERT L      |                  |  |
|                 | ONSHIRE STREET<br>GE, CA 91325-1219 |                      | ART UNIT              | PAPER NUMBER     |  |
|                 | ,                                   |                      | 3736                  |                  |  |
|                 |                                     |                      | DATE MAILED 12/15/200 |                  |  |

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |  | Application No.  | Applicant(s)   |              |  |  |
|--|--|--|--|--------------|--|--|
| Office Action Summary  |  | 10/034,740   | ENEGREN ET AL.   |              |  |  |
|  |  | Examiner   | Art Unit   |              |  |  |
|  |  | Robert L. Nasser   | 3736   |              |  |  |
| The MAILING Period for Reply   | DATE of this communication app   | ears on the cover sheet with   | the correspondence addi  | ress         |  |  |
| THE MAILING DATE  - Extensions of time may be after SIX (6) MONTHS fro  - If the period for reply spec  - If NO period for reply is sp.  - Failure to reply within the Any reply received by the | ATUTORY PERIOD FOR REPLY E OF THIS COMMUNICATION. e available under the provisions of 37 CFR 1.13 m the mailing date of this communication. iffied above is less than thirty (30) days, a reply secified above, the maximum statutory period we set or extended period for reply will, by statute, Office later than three months after the mailing ment. See 37 CFR 1.704(b). | 6(a). In no event, however, may a rep<br>within the statutory minimum of thirty (<br>ill apply and will expire SIX (6) MONTH<br>cause the application to become ABAI | oly be timely filed  (30) days will be considered timely.  HS from the mailing date of this com  NDONED (35 U.S.C. § 133). | ımunication. |  |  |
| Status   |  |  |  |              |  |  |
| 1)⊠ Responsive to  | communication(s) filed on 21 Se  | ptember 2004.  |  |              |  |  |
| 2a) This action is   |  | action is non-final.   |  |              |  |  |
|  | Since this application is in condition for allowance except for formal matters, prosecution as to the medits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |  |              |  |  |
| Disposition of Claims  |  |  |  |              |  |  |
| 4a) Of the above 5) ☐ Claim(s) ☐ Claim(s) 1-11 7) ☐ Claim(s) ☐   | and 21-23 is/are rejected.   | n from consideration.  | -  | ·            |  |  |
| Application Papers   |  |  |  |              |  |  |
| 9) ☐ The specification   | on is objected to by the Examine   | :  |  |              |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |  |  |  |              |  |  |
| Applicant may r  | not request that any objection to the o  | Irawing(s) be held in abeyance   | e. See 37 CFR 1.85(a).   |              |  |  |
|  | awing sheet(s) including the correcticle claration is objected to by the Example 1   | •  | •  | • •          |  |  |
| Priority under 35 U.S.C  | . § 119  |  |  |              |  |  |
| a) All b) So  1. Certified  2. Certified  3. Copies of applications.   | ent is made of a claim for foreign ome * c) None of: I copies of the priority documents of the certified copies of the priority documents of the certified copies of the priorion from the International Bureau d detailed Office action for a list of   | have been received. have been received in Applity documents have been received in Applity documents have been received.  | plication No<br>eceived in this National S   | taçıe        |  |  |
| Attachment(s)  |  | ,  |  |              |  |  |
| <ol> <li>Notice of References C</li> <li>Notice of Draftsperson's</li> </ol>   | ited (PTO-892)<br>s Patent Drawing Review (PTO-948)  |  | mmary (PTO-413)<br>Mail Date   |              |  |  |
| _  | Statement(s) (PTO-1449 or PTO/SB/08)   |  | ormal Patent Application (PTO-1  | 152)         |  |  |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/21/2004 has been entered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6-8, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Savage et al 5830209. Savage et al shows an implantable sensor system for taking readings from a patient including implantable sensors 52 and 54 at the distal tip of element 34, where the tip contacts bodily fluids, a flush sleeve 22 for directing flushing fluid to the tip (see column 7, lines 6-19) where the sensor and the flush sleeve are concentric. With respect to claim 2, there is a connector fitting 16 which helps support the sensors in the body. With respect to claim 4, the outer sleeve 2 and the sensor are in a "tight" fit arrangement. With respect to claim 6, the sleeve 22 is proximal to the sensor. With respect to claim 7, there is a protective sleeve 14. With respect to claim 8, it is inherent that there is a connector fitting for connecting the fiber 34 to the source/detector of the light. Claims 21 and 2 are rejected for the reasons given above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al in view of Odell et al 2003/012025. Odell further teaches a known method for delivering a flushing solution is to pierce a septum with a need le to deliver the fluid. (see paragraph 27). Hence, it would have been obvious to modify Savage et al to deliver the fluid through a septum, to protect the lumen and prevent contamination.

Claims 5 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al in view of Masterson et al 5891094. In figures 18 and 19 and the accompanying discussion, Masterson et al further shows a one way valve in the flush line to prevent back wash of the flushing solution. Hence, it would have been obvious to modify Savage to use such a one way valve, to ensure proper flushing operation.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al in view of Newman et al 6358244. Newman et al et al teaches that saline is a known flush solution (see column 5, lines 47-65). Hence, it would have been obvious to modify Savage to use heparin, as it is merely the substitution of one known equivalent fluid for another.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al in view of Riccitelli et al 5166990. Riccitelli et al teaches that heparin is a known flush solution (see column 2, lines 39-64). Hence, it would have been obvious to modify

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Savage to use heparin, as it is merely the substitution of one known equivalent fluid for another.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al in view of Wulfman et al 2002/0007190. Wulfman further teaches the equivalence of wireless or wired connection between implanted temperature sensors and the monitor (see paragraph 145). Hence, it would have been obvious to modify Savage to use a wireless connection, as it is merely the substitution of one known equivalent transmission means for another.

Applicant's arguments filed 9/21/2004 have been fully considered but they are deemed moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser Primary Examiner Art Unit 3736

Robot & Meon

RLN December 13, 2004

> ROBERT L. NASSER PREMARY EVAMINER